

REMARKS

Claims 30-106 are now pending in this application. Claims 1-29 have been cancelled.

Rejection Under 35 U.S.C. § 102

Claims 30, 31, 33-63, 65-97 and 101-106 were rejected under 35 U.S.C. § 102(e) as being anticipated by Schreck et al., U.S. Publication No. 2002/0107531 (hereinafter "Schreck").

Applicants respectfully submit that Schreck does not sufficiently disclose how to treat a patent foramen ovale (PFO) and thus is not sufficiently enabling prior art.

Every embodiment disclosed in Schreck is exclusively directed to mitral valve repair. Schreck *fails to disclose a single embodiment* that is directed to closure of a PFO. Despite this, the Office Action argues that the "entire document" of Schreck discloses a method for treating PFO.

There are actually *only three sentences* throughout Schreck that mention the term PFO. Each of these sentences is purely conclusory in nature and utterly fails to enable the closure of a PFO. Schreck says that "the invention can be used to repair arterial septal defects (ASD), ventricular septal defects (VSD), and in cases involving patent foramen ovale," (Schreck [0009]) and "[a]s those skilled in the art will appreciate, the present invention may similarly used (sic) to repair Arterial Septal Defects (ASD), Ventricular Septal Defects (VSD), and defects associated with Patent Foramen Ovale (PFO)," (Schreck [0038]) and "[s]imilarly, the present invention maybe (sic) used to repair ventricular septal defects, or defects relating to patent foramen ovale" (Schreck [0041]).

A mitral valve is not a patent foramen ovale. Each is significantly different at least in function, anatomy and position within the body. Applicants respectfully submit that Schreck's mere mention of the term "patent foramen ovale," without further description, does not and cannot sufficiently enable Schreck as prior art to the present claims. The Federal Circuit has made it clear that mere mention of an alternative, without sufficiently describing that alternative, does not constitute an enabling disclosure. See, e.g., Medtronic Navigation, Inc. v. Brainlab Medizinische Computersysteme GMBH, 222 Fed. Appx. 952, 956 (Fed. Cir. 2007). Schreck's disclosure mirrors that at issue in Medtronic. There, the patent was exclusively directed to use of an acoustic system, and merely mentioned that optical systems could serve as an alternative. The court stressed that,

despite mentioning the optical-based alternative, there was "no enabling description of how to make and use" any optically-based alternatives. Id. This is precisely the situation here. Nowhere within Schreck is there a description of how to apply Schreck's device to treat PFO, and the three sentences merely constitute a laundry list of alternative uses without the description necessary to enable those alternatives.

Further, the Office Action has failed to provide any evidence that Schreck satisfies the "undue experimentation" test for enablement, following In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) and MPEP §2164.01 "Test of Enablement." Given that Schreck is limited to the bald assertion that "those skilled in the art will appreciate" how to apply the device, and fails to provide any further description, the Office Action has failed to properly set forth a *prima facie* rejection of the claims.

Therefore, since Schreck does not sufficiently enable how to treat PFO, Schreck does not anticipate each and every element of claim 30. Accordingly, Applicants respectfully submit that Schreck altogether fails to disclose the elements of claims 31, 33-63, 65-97 and 101-106 by virtue of their dependence upon claim 30, and respectfully request that the Examiner's rejections of claims 30, 31, 33-63, 65-97 and 101-106 be withdrawn.

Rejection Under 35 U.S.C. § 103

Claims 64 and 98-100 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Schreck and claim 32 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Schreck in view of Berg et al., U.S. Patent 6712836 (hereinafter "Berg").

Regarding claims 64 and 98-100, Applicants respectfully submit that since claims 64 and 98-100 depend on claim 30, that Schreck fails to establish a *prima facie* case for obviousness, due to the same reasons regarding claim 30 above. Therefore, Applicants respectfully request that Examiner's rejections of claims 64 and 98-100 be withdrawn.

Conclusion

Prompt and favorable action on the merits of the claims is earnestly solicited. Should the Examiner have any questions or comments, the undersigned can be reached at (949) 567-6700. The Commissioner is authorized to charge any fee which may be required in connection with this Amendment to deposit account No. 15-0665.

Respectfully submitted,

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